II. Amendments to the claims and cancelled claim 8

Support for recitation of a uniform distance provided by "a plurality of contiguous geometric structures provided upon the material, wherein each perforation of the plurality of staggered perforation is located within a geometric structure of the plurality of contiguous geometric structures", in amended claim 1, can be found at least by the disclosure at page 22, lines 21-30 and Figures 1-3 of the specification.

Support for recitation of "a plurality of contiguous geometric structures drawn, printed or etched upon the material" in amended claim 5 can be found at least at page 22, lines 28-29 of the specification.

Support for "plurality of contiguous geometric structures is a plurality of circles" in amended claim 7 can be found at least at page 22, line 24, Figures 1-3 and original claim 8 of the specification.

Support for "transparent" and "wherein the perforations are sized to permit the tip of a marker therethrough" can be found at least at page 22, line 22 and page 22, lines 31-32 of the specification.

Claim 8 is hereby cancelled without prejudice or disclaimer.

III. Rejection of claims 1-3, 5 and 7-10 under 35 U.S.C. 102(b)

The Office Action rejects claims 1-3, 5 and 7-10 under 35 U.S.C. 102(b) as being anticipated by Hsia (US Patent No. 4,736,526). Applicants traverse this rejection.

In order to be anticipatory reference, every element recited in the claims must be found either expressly or inherently described in a single prior art reference. Every element recited in the claims is not found either expressly or inherently in Hsia. Claims 1, 5, 7, 9 and 10 are amended to solely expedite prosecution and in order to more clearly define particular aspects of the invention.

Hsia is directed to providing an apparatus "to enable a user to readily draw common geometric figures" (Abstract), that is, Hsia discloses a drafting tool (col. 2, line 42). Hsia has nothing to do with assisting administration of a botulinum toxin. There is no disclosure or suggestion in Hsia related to the medicinal arts, let alone botulinum toxin administration, as recited in all of the instant claims. Thus, Hsia is non-analogous art, cited only by parsing out particular elements/limitations in the instant claims and comparing them, out of context, to various elements allegedly present in Hsia, elements of the device of Hsia also analyzed out of their context of the Hsia patent.

Also, there is no disclosure in Hsia relating to "a plurality of contiguous circles rendered upon the material and the perforations are located in the center of the circles", despite the Office Action's assertions in the paragraph bridging pages 2 and 3 of the Office Action. The Office Action appears to misconstrue the template configuration disclosed in Hsia, which shows perforations on a swinging arm of a drafting tool, which are used to draw circles of various sizes.

As Hsia does not disclose staggered perforations spaced apart by a uniform distance provided by a plurality of contiguous geometric structures provided upon the material, wherein each perforation of the plurality of staggered perforation is located within a geometric structure of the plurality of contiguous geometric structures, as presently recited in claim 1. As such, Hsia cannot anticipate claim 1 or claims dependent therefrom.

Similarly, Hsia also does not disclose or suggest staggered perforations spaced apart by a uniform distance provided by a plurality of contiguous geometric structures drawn, printed or etched upon the material, as recited in claim 5. It appears that in fact there are no geometric structures drawn, printed or etched upon the material of Hsia, only cut-outs. Accordingly, Hsia cannot anticipate claim 5 or any claims dependent therefrom.

Hsia does not disclose a plurality of contiguous circles are rendered upon a material where the perforations are located in the center of the rendered circles and wherein the perforations are sized to permit the tip of a marker therethrough, as recited in claim 10 and claims dependent therefrom.

Thus, this rejection should be withdrawn.

IV. Rejection of claims 1-3, 5 and 7-10 under 35 U.S.C. 102(b)

The Office Action rejects claims 1-3, 5 and 7-10 under 35 U.S.C. 102(b) as being anticipated by Williamson (US Patent No. 4,580,561). Applicants traverse this rejection.

As above, in order to be anticipatory reference, every element recited in the claims must be found either expressly or inherently described; in a single prior art reference. Every element recited in the claims is not found either expressly or inherently described in Williamson. Claims 1, 5, 7, 9 and 10 are amended solely to expedite prosecution and in order to more clearly define particular aspects of the invention.

The device in Williamson is directed to a system by which surgical instruments are implanted into a body tissue, more particularly to a planning bridge and implant needle applicator. There is no mention of botulinum toxin therapy to be found in Williamson, but rather a device and method for defining and administering surgical instruments in and along aligned tissue entrance and exit points along a linear path (see col. 3, second paragraph).

Also, there is no disclosure in Williamson relating to “a plurality of contiguous circles rendered upon the material and the perforations are located in the center of the circles”, despite the Office Action’s assertions in the paragraph bridging pages 3 and 4 the Office Action. The Office Action appears to misconstrue the template configuration disclosed in Williamson much like in Hsia, where the Office Action defines the perforations in the cited references to be both the perforation and define a circle. The Office Action is again taking atomized elements (perforations) from the cited art and applying them out of context to elements recited in the pending claims in order to align the disclosure with the instant claims.

As Williamson clearly does not disclose staggered perforations spaced apart by a uniform distance provided by a plurality of contiguous geometric structures provided upon the material of the device, wherein each perforation of the plurality of staggered perforation is located within a geometric structure of the plurality of contiguous geometric structures, as presently recited in claim 1, Williamson cannot anticipate claim 1 or claims dependent therefrom.

Similarly, Williamson also does not disclose or suggest staggered perforations spaced apart by a uniform distance provided by a plurality of contiguous geometric structures drawn, printed or etched upon the material, as recited in claim 5. It appears that in fact there are no geometric structures drawn, printed or etched upon the material of Williamson, only perforations. Accordingly, Williamson cannot anticipate claim 5 or any claims dependent therefrom.

Additionally, the Office Action's deeming of the material in Williamson as flexible goes directly against the principles of operation of the device in Williamson. The flexibility of the bridging plates, or rods supporting them, would be undesirable in the device in Williamson, as it is made clear that defining linear paths, between corresponding perforations in the two bridging plates, is what is desired and expected. In fact, it is stated in Williamson at col. 5, lines 42-49, that "The apertures 38 are bored normal to the surfaces of plates 34a and 34b which have sufficient thickness such that alignment of instruments 42 perpendicular to the surfaces of the bridge plates is automatic. These marks indicate the entry and exit points for the surgical instrument to be implanted and thus define a linear path through the body tissue to be treated." Accordingly, such a disclosure would direct one to/suggest *inflexible* plates in order to provide/maintain a linear path between exactly aligned apertures, bored normal in a plate having a sufficient thickness such that alignment of instruments perpendicular to the surfaces of the bridge plates is automatic. The Office Action's deeming the material in Williamson "…to be flexible since the degree of flexibility is not disclosed and claimed therefore if the material is capable of being flexed then the

material is deemed flexible." (Office Action, page 3, lines 15-17) does not have any basis in Williamson. Indeed, properly taking the disclosure of Williamson holistically directs one to inflexible materials, not flexible ones. Accordingly, Williamson cannot anticipate claims 3 and 5, as well as claims depending therefrom.

Williamson clearly does not disclose a plurality of contiguous circles rendered upon a material where the perforations are located in the center of the rendered circles and wherein the perforations are sized to permit the tip of a marker therethrough, as recited in claim 10 and claims dependent therefrom. There is no mention of rendering circles around the perforations disclosed in Williamson. Also, there is no disclosure teaching or suggesting that the material with perforations of Williamson is transparent. Therefore, Williamson cannot anticipate claim 10 or any claim depending therefrom.

Thus, this rejection should be withdrawn.

V. Rejection of claims 16, 18 and 20 under 35 U.S.C.103 (a)

The Office Action rejects claims 16, 18 and 20 under 35 U.S.C. 103(a) as being unpatentable over Hsia or Williamson as applied to claims 1, 5 and 10. Applicants traverse this rejection.

As detailed above, there is no disclosure or suggestion in either Hsia or Williamson related to a device for assisting administration of a botulinum toxin in accordance with the instant claims. Hsia relates to a drafting tool to enable a user to readily draw common geometric figures and Williamson relates to a system that utilizes aligned perforated bridging plates to define linear pathways through which surgical instruments are introduced into tissue.

The Office Action fails to establish a prima facie case of obviousness of claims 16, 18 and 20, as its application of Hsia or Williamson, alone or even in combination, does not suggest or even relate to the instantly claimed device. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The Office Action has not established such suggestion or motivation, either in the references themselves or in knowledge generally available to one of ordinary skill in the art. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As stated above, neither Hsia nor Williamson teach or suggest a device having the various elements, as presently claimed, for assisting administration of

a botulinum toxin. Claims in dependent form are construed to include all the limitations of the claim incorporated by reference into the dependent claim.

Accordingly and at least for the following reasons, neither Hsia nor Williamson teach or suggest botulinum toxin administration guides having 40, 60 or 80 perforations, wherein the perforations are staggered and spaced apart by a distance provided by a plurality of contiguous geometric structures provided upon a material, where each perforation of the plurality of staggered perforation is located within a geometric structure of the plurality of contiguous geometric structures (Claim 16). Likewise, neither Hsia nor Williamson teach or suggest a botulinum toxin guide having 40, 60 or 80 perforations where the material of the device includes a plurality of staggered perforations which extend completely through the material from the upper face to the lower face, the staggered perforations being spaced apart by a uniform distance provided by a plurality of contiguous geometric structures drawn, printed or etched upon the material (claim 18), nor a botulinum toxin injection guides having a plurality of contiguous circles are rendered upon the transparent material of the device and where the perforations are located in the center of the circles and wherein the perforations are sized to permit the tip of a marker therethrough (claim 20). Since such limitations are not found in the cited references, nor are shown by the Office Action to be general knowledge in the art, the botulinum toxin injection guide of the instant claims cannot be held as obvious in light of the limited disclosures of Hsia or Williamson.

Thus, this rejection should be withdrawn.

VI. Rejection of claims 15, 17 and 19 under 35 U.S.C.103 (a)

The Office Action rejects claims 15, 17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Hsia or Williamson. Applicants traverse this rejection.

As discussed above, neither Hsia nor Williamson disclose or suggest a botulinum toxin injection guide having all of the recited elements of the instant claims. As above, claims in dependent form are construed to include all the limitations of the claim incorporated by reference into the dependent claim.

Accordingly, claim 15 includes the limitation of staggered perforations spaced apart by a distance provided by a plurality of contiguous geometric structures provided upon a material, where each perforation of the plurality of staggered perforation is located within a geometric structure of the plurality of contiguous geometric structures, the space of the perforations being 1.5 or 2.0 cm apart. There is no such disclosure to be found or suggested by Hsia or Williamson. Likewise, claim 17 includes the limitations where the material of the device includes a plurality of staggered perforations which extend completely through the material from the upper face to the lower face, the staggered perforations being spaced apart by a uniform distance provided by a plurality of contiguous geometric structures drawn, printed or etched upon the material, the spaces between the perforations being 1.5 or 2.0 cm. No such disclosure is to be found or suggested by Hsia or Williamson. Claim 19 includes the limitations of a plurality of contiguous circles rendered upon transparent material of the device, where the perforations are located in the center of the circles, where the perforations are sized to permit the tip of a marker therethrough, the spaces between the perforations being 1.5 or 2.0 cm. If such elements cannot be found in the cited references, the claims reciting such limitations cannot be held as obvious in light of this lack of disclosure.

Thus, this rejection should be withdrawn.

VII. Conclusion

All issues raised in the Office Action have been addressed. Allowance of claims 1-3, 5, 7, 9-10 and 15-20 is respectfully requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

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